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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,980	03/13/2001	Peter Andersen	670001-2002.4	9361
20999	7590	02/10/2004		
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
DATE MAILED: 02/10/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/804,980

Applicant(s)

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3November2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-11,26,28,30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-11,26,28,30,32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicants' Response to Office Action, received 3 November 2003, is acknowledged.

Claims 7, 8, 12-25, 27, 29, 31, and 33 have been cancelled.

2. Claims 1-6, 9-11, 26, 28, 30, and 32 are pending and under consideration.

**Rejections Withdrawn**

3. The rejection of claims 1, 2, 4, 6, and 9-11 under 35 U.S.C. 112; second paragraph, as being indefinite for a "substantially pure" polypeptide is withdrawn.

Applicants argue that the term "substantially pure" is definite in that the claimed compositions would not include other polypeptide materials except perhaps small amounts thereof as described in the specification at page 6, lines 13-20.

The examiner has considered applicants' argument, and finds it persuasive.

**Rejections Maintained**

4. The rejection of claims 1-6, 9-11, 26, 28, 30, and 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 18-30 of U.S. Patent No. 5,955,077 is maintained.

The submitted Terminal Disclaimer was not submitted as a separate document, but improperly submitted as part of the remarks section of applicants' instant response. Therefore, the Terminal Disclaimer was disapproved.

5. The rejection of claims 4, 6, and 9-11 under 35 U.S.C. 112, second paragraph, as being indefinite for a "substantially pure" polypeptide and a fragment is "derived" from a virulent mycobacterium is maintained.

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Applicants argue that the term "substantially pure" is definite in that the claimed compositions would not include other polypeptide materials except perhaps small amounts thereof as described in the specification at page 6, lines 13-20.

The examiner has considered applicants' argument, and finds it persuasive.

Applicants argue that "derived" is supported in view of the general guidance contained in the specification and by those of ordinary skill in the art and that prior U.S. Patents also contain "derived" in claims.

The examiner has considered applicants' remarks concerning "derived", but does not find it persuasive. Each patent application and its claims are prosecuted on their own merits. The instant claim 4 is drawn to any polypeptide fragment "derived" from a virulent mycobacterium. It remains unclear as to the identity of the "any polypeptide fragment derived" because there is no definition of derivation, i.e., is the polypeptide fragment isolated/purified from mycobacteria or a fragment produced by macrophages infected with mycobacteria.

#### **Claim Notation**

6. It is noted that claim 2 recites "A substantial pure polypeptide". It is recommended that the claim be amended to recite "substantially" in order to conform to the other claims' language.

#### **Conclusion**

7. Claims 1-6, 9-11, 26, 28, 30, and 32 are finally rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (571) 272-0865.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

February 9, 2004